

REMARKS

Claims 19-24 were pending in the present application. Claim 19 has been amended to recite that the pharmaceutical carrier device is “free of plasticizer.” Support for this amendment is found in the subject application in Examples 12-14, among other places. In addition, claim 19 has been amended to provide the proper antecedent basis for “treatment site” and claim 22 has been amended to provide the proper Markush group language. Furthermore, new claims 34-40 have been added to individually list each film forming and bioadhesive polymer in the Markush groups of claim 22. New claims 40-42 incorporate the subject matter of original claim 25. Accordingly, no new matter has been added by this amendment. Consequently, claims 19-24 and 34-42 are currently under consideration.

CLAIM REJECTIONS

Claim 22 Under 35 U.S.C. 112, Second Paragraph

Claim 22 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to include the proper Markush group language. Claim 22 has been amended to recite “selected from the group consisting of” in the appropriate places to provide the proper Markush group language. Thus, withdrawal of the rejection is respectfully requested.

Claims 19-24 Under 35 U.S.C. § 102(b)

Claims 19-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 95/05416 (‘416). Specifically, the Office Action States:

“‘416 teaches treatment of a mucosal surface composition comprising an adhesive layer and other layers, which are water-soluble and contain an active (abstract).”

“Hydroxypropyl cellulose in combination with sodium-CMC is disclosed (page 12) line 29 and page 13 line 1). Thicknesses are specified (page 13 lines 11-12). Hydroxypropyl cellulose is disclosed in a second layer (page 15 lines 7-16). An overlapping

adhesive layer is specified (page 30, lines 16-21). Anesthetics are specified (page 9, lines 21).”

As amended, claim 19 recites that the layered pharmaceutical carrier device is free of a plasticizer. Support for this amendment is found in Examples 12-14, among other places. As such, it is no longer anticipated under Section 102. “A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” See MPEP § 2131 (citing *Verdegaal Bros. v. Union Oil of Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Here, the ‘416 patent fails to describe a required element of claim 19. In particular, ‘416 does not disclose a layered pharmaceutical carrier device that is free of a plasticizer. ‘416 only teaches laminated devices that include pressure sensitive adhesives made tacky by the addition of a water soluble plasticizer. Glycerin is the preferred plasticizer, but examples of other suitable plasticizers, such as sorbital, other glycols, polysorbate 80, triethyl titrate, acetyl triethyl titrate, and tributyl titrate are also described. Thus, the ‘416 patent is distinguished by the present amendment to the claims.

Based on the foregoing, ‘416 does not describe or suggest all the claim limitations as required under 35 U.S.C. § 102(b). Withdrawal of the rejection of claim 19 is respectfully requested.

Since claims 20-24 include each of the features and limitations of claim 19, these claims are also not anticipated by ‘416. Thus, reconsideration and withdrawal of the rejections of claims 20-24 is also respectfully requested.

SUMMARY

Applicants have by way of the amendments and remarks presented herein, made a sincere effort to overcome rejections and address all issues that were raised in this Office Action. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If

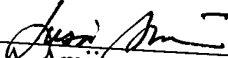
it is determined that a telephone conversation would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 359872000810. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

19. (Amended) A method for treating a treatment site of mucosal surfaces, surrounding tissues, and bodily fluids, comprising applying an adherent film at the treatment site for the protection of said treatment site and delivery of pharmaceutical to said mucosal surface, said surrounding tissues, and said bodily fluids, said adherent film comprising a layered pharmaceutical carrier device which is water-erodable and free of a plasticizer.

22. (Amended) The method of claim 21, wherein said first water-erodable adhesive layer comprises a film forming polymer selected from the group consisting of hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, [or] and hydroxyethylmethyl cellulose, alone or in combination, and a bioadhesive polymer selected from the group consisting of polyacrylic acid, polyvinyl pyrrolidone, [or] and sodium carboxymethyl cellulose, alone or in combination.